UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

Ronaldo Ligons, et al.,

Plaintiffs,

vs.

Minnesota Department of Corrections, et al.,

Defendants.

Civil File No. 15-CV-2210 (PJS/BRT)

SECOND AFFIDAVIT OF DR. DAVID A. PAULSON, M.D., M.B.A.

STATE OF MINNESOTA)
)ss.
COUNTY OF RAMSEY)

DAVID PAULSON, M.D., M.B.A., being first duly sworn, deposes and states as follows:

1. I am the Medical Director for the Minnesota Department of Corrections (DOC). I have held the position of Medical Director since 1995. This affidavit is based on my personal knowledge and review of records maintained in the ordinary course of business by the DOC.

2. I am a licensed physician in the State of Minnesota and am Board certified in Internal Medicine, with specialties in Primary Care Medicine and Health Care Delivery Management. A true and correct copy of my curriculum vitae is attached hereto as Exhibit A, with personal information redacted.

3. Attached hereto as Appendix A is a glossary of selected medical and correctional terms used in this Affidavit.

I. MEDICAL CARE AT THE MINNESOTA DEPARTMENT OF CORRECTIONS.

4. The DOC provides primary health care to inmates through the use of contractors.[1] In the past, the DOC has contracted with Correctional Medical Services, Inc. (CMS), Corizon Health, Inc. (Corizon), and Centurion, LLC. The DOC currently contracts with Centurion. Centurion provides on-site medical practitioners, including medical doctors, physicians assistants, and nurse practitioners.

5. Generally, the DOC does not have protocols for medical treatment. The DOC expects Centurion medical practitioners, who provide direct patient care to inmates, to use their own medical judgment and discretion in directing medical treatment. I do not supervise the Centurion medical practitioners who provide direct patient care at the DOC. Centurion has a Medical Director who supervises its medical practitioners. Any concerns that I have as the DOC's Medical Director regarding a practitioner's performance are raised and addressed through the contract vendor. The only medical employees I supervise are the Advanced Practice Registered Nurses (hereinafter "nurse practitioners") who are employed by the DOC. The relationship between the DOC and contract vendors was the same under prior contracts.

6. The DOC has a formulary of preferred medicines. The formulary is a list of prescription drugs – both generic and brand name – established by the Pharmacy & Therapeutics Committee (P&T Committee), of which I am the chair – for use within the

[1] Because the DOC does not provide health care to offenders who are on supervised release in the community, this Affidavit uses the term "inmates" to refer to individuals in Minnesota prisons.

DOC. The P&T Committee is a multidisciplinary group including representatives from both the DOC and Centurion. The P&T Committee includes members who are licensed physicians, pharmacists, and registered nurses. Doctors, physician assistants, and nurse practitioners at the DOC can request non-formulary prescription drugs, and the request is evaluated by Centurion. I have authority to override Centurion's decision about whether a non-formulary prescription drug should be filled.[2] Inmates can discuss their medical care and treatment with on-site medical practitioners and/or submit kites or grievances in accordance with DOC policy for any disagreements over the prescription of any drugs, whether formulary or non-formulary. The DOC's formulary can be overridden, and medication decisions are ultimately made on a case-by-case basis. DOC inmates receive non-formulary prescription drugs when medically appropriate. Just because a prescription drug is considered non-formulary does not mean that it is not routinely prescribed and dispensed when medically necessary. I often approve non-formulary prescriptions.

7. In my role as the DOC's Medical Director, I serve as a consultant to the contractor's medical practitioners. I report to Nanette Larson, the DOC's Health Services Director. I routinely educate the DOC-employed nursing staff and attend meetings with Centurion practitioners, both one-on-one and during monthly group meetings. I also routinely consult with the Medical Director at Centurion and meet biweekly with Ms. Larson and Centurion about mutual procedural, programming, and recruitment

[2] I had this same authority under the DOC's previous agreements with contractors.

issues. I also receive and review certain inmate complaints and grievances as they are referred to me through a triage process. In certain instances, I assist Ms. Larson, and others, in responding to kites or grievances from inmates. The P&T Committee includes DOC representatives and contracted vendor representatives. The P&T Committee approves the DOC's formulary, which is the preferred list of medications for treatment in the DOC. The P&T Committee also approves the stock medication list, which is the list of medications the DOC can have on hand as a stock supply. The P&T Committee also reviews standing orders. Additionally, I review infection control reports, review pharmacy data, draft and execute standing orders for treatment that can be ordered by nursing staff, and monitor prescriptions for narcotics and other selected medications and classes of medications within the DOC.

8. Except in unusual circumstances, I do not personally diagnose or treat any patients within the DOC. I rely on the Centurion medical practitioners to diagnose and treat patients. I expect Centurion medical practitioners to send me any medical records they believe are medically significant with regards to HCV.

II. HEPATITIS C

A. Types of Viral Hepatitis And Transmission.

9. Bloodborne pathogens are pathogenic microorganisms present in blood and/or body fluids that can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV). Bloodborne pathogens can be present in many human body fluids (e.g., joint fluid, semen, cerebral spinal fluid, and ascites), blood, and

products derived from human blood, such as blood plasma. Needlesticks, percutaneous injuries, and mucus membrane exposures (i.e., blood or body fluid in an individual's mouth, vagina, or eye) may expose an individual to bloodborne pathogens. Bloodborne pathogens are not spread by saliva, tears, or urine unless visibly contaminated with blood.

10. The term "hepatitis" means inflammation of the liver, and is also the name of a family of viral infections that affect the liver, including Hepatitis A, B, and C. Hepatitis C is a form of viral hepatitis and a blood-borne pathogen primarily transmitted through infected blood or body fluids that affects the liver as its primary target organ. The modes of transmission of HCV are clear and well understood. HCV is generally spread through percutaneous (through the skin) exposures, such as through injection drug use or the use of contaminated needles, ink, or equipment in tattooing or body piercing. Individuals who received clotting factor concentrates before 1992 or solid organ transplants before 1987, when screening for HCV became available for the respective procedures, are also at an increased risk of HCV. (*See* Appendix ¶ J (describing clotting factors).) Sexual contact is not an efficient means of transmission, meaning that the risk of transmission through such activities is extremely low. Casual contact in the household setting such as sharing of eating utensils, coughing, sneezing, casual contact such as kissing, hugging, or shaking hands, insect bites, and consumption of food or drink do not present risks for transmission of HCV. Transmission among individuals sharing personal care items with another's blood, such as razors or toothbrushes, is possible though extremely rare.

11. In my 23 years as Medical Director of the DOC, I have never heard of transmission of Hepatitis C from one inmate to another inmate through casual contact such as sharing common items in an environment or having a roommate with HCV. Nor have I learned of an inmate becoming infected with HCV through a fight with another inmate or with staff. Additionally, I am not aware of any inmate who has been infected by Hepatitis C through illicit tattooing, sexual contact, or injection drug use within a DOC facility, both of which are prohibited activities under DOC rules. DOC rules also prohibit sexual contact between inmates.

12. HCV is divided into multiple strains or genotypes and subtypes, all of which share similarities but are genetically distinct. The virus's genotype is the genetic makeup up of the particular strain infecting an individual. There are at least six genotypes of HCV, including 1, 2, 3, 4, 5 and 6, and more than 50 subtypes. A subtype is identified by the genotype and a letter (i.e., 1a, 1b, 2a, 2b, etc.). Genotype 1 is the most common in the United States and makes up roughly 75% of all HCV infections in the country. The remaining individuals infected in the United States generally carry genotypes 2 and 3. "Superinfection," or co-infection with more than one genotype of HCV, is possible but relatively rare. An individual who is infected with HCV always has the same genotype of HCV as the person whose blood infected him or her and does not change.

13. Not everyone who is infected with HCV will develop a chronic HCV infection. Approximately 25-30% of persons infected with HCV will clear the infection on their own, without any treatment. The remaining 70-75% of patients will develop

chronic HCV infection. Hereinafter, the term "HCV" with reference to a patient or DOC inmate means only those individuals who have not eradicated the disease and have a chronic HCV infection.

B. Evidence-Based Monitoring Of Hepatitis C Patients.

14. HCV is a slowly progressing disease and most patients (between 70 and 80%) do not report any subjective symptoms. In some patients HCV does not progress at all. In some patients the virus can remain dormant for many years. Those patients who do develop symptoms may report fatigue, nausea, loss of appetite, or joint pain. Such symptoms are not specific to HCV and are present in many medical conditions.

15. For the vast majority of patients infected with HCV, the virus does not cause life-threatening complications. Of the HCV patients who develop advanced liver disease, a subset will develop liver failure or liver cancer. However, progression of HCV is generally very slow, occurring over decades, and does not progress at all in some patients.

16. The biggest factor in the rate at which HCV progresses, if at all, is a patient's consumption of alcohol. Based on my experience as the DOC's Medical Director, and my other training and experience as a physician outside of the DOC, individuals with HCV who are incarcerated by the DOC are less likely to progress in their disease than patients in the general population because inmates cannot consume alcohol unless they do so illicitly within the prison. The DOC's Offender Discipline Rules prohibit the possession and consumption of alcohol.

17. In addition to behavioral controls related to alcohol and drug use in place within the DOC that impact the progression of HCV and liver disease, the medical care within the DOC also slows the already-slow progression of HCV when compared to individuals in the community. Inmates receive medical treatment for comorbid conditions such as HBV, HIV, and insulin resistance that many would not receive in the community. (*See* Appendix ¶ DD (defining insulin resistance).) Moreover, the controlled prison environment means that many inmates are removed from environmental toxins that may impact liver function.

18. One condition that may affect HCV patients is chronic liver disease. Chronic liver disease is measured by the degree of fibrosis in the liver. Liver fibrosis is the accumulation of scar tissue in the liver caused by inflammation.

19. Liver damage is classified by grade and stage determined by a pathologist's microscopic (histological) examination of liver tissue obtained by biopsy. Microscopically, the liver is composed of thousands of "lobules" or groups of liver cells roughly hexagonal in shape that are separated by connective tissue. The lobules have a blood supply and a bile duct that drains the bile toward the intestine and gallbladder. Grade refers to the amount of inflammation, which is primarily determined by the increased number of white blood cells in the lobule area. Grade 0 means no inflammation or that the liver has a normal appearance. Grade 4 means a large amount of inflammation. Stage refers to the amount of scarring and liver cell damage in the lobule area. Stage 0 means no scarring or that the liver has a normal appearance. Stage 4 means a large amount of scarring and liver cell damage, which is often referred to as cirrhosis.

The grade and stage is not an indicator of liver function. The liver has a tremendous reserve capacity and can provide essential functions despite microscopic evidence of even severe liver damage. The liver has a high regenerative capacity, including the ability to regenerate damaged tissue and restore normal tissue.

20. Ultrasound elastography is a tool developed relatively recently to assess hepatic fibrosis as an alternative to liver biopsy. An elastography device sends ultrasonic waves through the liver to estimate the amount of fibrosis. Shear wave elastography generates waves through tissue and measures stiffness by measuring the speed of the shear waves in the tissue. The technology allows practitioners to assess liver fibrosis in a non-invasive manner and reports stages of fibrosis.

21. A number of other non-invasive tests have been developed for the evaluation of patients' liver disease. These tests include a commercially-available serum marker test known as FibroSure which is patented and can be performed only in validated laboratories. A FibroSure test analyzes a patient's blood and results in a score that correlates results with the stage of fibrosis that would be seen on a liver biopsy. The score directly correlates with the stages of liver disease F0, F1, F2, F3, and F4. Based on my medical experience and talking to other practitioners in my field, I understand that FibroSure overestimates the degree of fibrosis as compared to ultrasound elastography and liver biopsy (i.e., FibroSure indicates that a patient has more advanced liver disease than would be indicated by elastography or biopsy). At the time of my previous Affidavit, the DOC was using FibroSure to evaluate inmates for immediate medical

treatment. The DOC is no longer ordering FibroSure tests or any other serum marker tests for inmates. The DOC is instead using ultrasound elastography to stage inmates.

22. A patient's degree of fibrosis can also be assessed through the use of a liver biopsy. In any of the four types of liver biopsies – percutaneous (through the skin), transjugular (through the jugular vein), laparoscopic (through incisions in the abdomen), open (through an incision and often incidental to another surgical procedure) – tissue samples are taken from the patient's liver through a biopsy needle or other tools. The tissue samples are then examined by a pathologist. In the past, the DOC ordered liver biopsies when appropriate to assess the degree of fibrosis present in an HCV-infected inmate's liver. However, with the development of non-invasive procedures which are generally accurate and well accepted in the medical community, the DOC has stopped ordering liver biopsies for most HCV-infected inmates.

23. A number of non-invasive or minimally invasive tests assist medical practitioners in estimating the degree of fibrosis in a patient's liver, including blood tests. Common blood tests include a liver panel, which, in turn, includes levels of:

- alanine aminotransferase (ALT)[3]
- aspartate aminotransferase (AST)[4]
- international normalized ratio (INR)[5]

[3] *See* Appendix ¶ B (defining ALT).
[4] *See* Appendix ¶ E (defining AST).
[5] *See* Appendix ¶ FF (defining INR).

Additionally, a patient's platelet count is frequently considered in estimating the degree of fibrosis in a patient's liver.[6]

24. Using the AST, ALT, and platelet count, practitioners commonly use two formulas to determine the likelihood of liver fibrosis or cirrhosis in patients with HCV. First, medical practitioners calculate an AST to Platelet Ratio Index (APRI) score to help predict significant hepatic fibrosis. The calculation uses a patient's AST level, the upper limit of normal for the test result, and platelet count. A Fibrosis-4 (FIB-4) score similarly assists medical practitioners in determining the probability of significant fibrosis, and also uses a patient's lab results and age. APRI and FIB-4 scores have been identified in medical literature as being an alternative to liver biopsy in terms of accuracy and predictive value of a patient's medical condition. These calculations do not measure severity of fibrosis, but are indicators of the likelihood or probability of significant fibrosis.

C. Medical Process for Screening for Hepatitis C Infection

25. The general medical process for identifying a patient with Hepatitis C involves two steps. The first step screens a patient for a past exposure to HCV by looking for antibodies to HCV in the blood,[7] which indicate that a patient has been infected with HCV either at some point in the past or has an active infection. A patient's test result on an HCV antibody test is reported as:

[6] *See* Appendix ¶ TT (defining platelets).
[7] *See* Appendix ¶ C (defining antibody).

- "non-reactive," meaning that the patient has never been infected with HCV and the HCV antibody is not present in the patient's blood;
- "reactive," meaning that the HCV antibody was found in the patient's blood; or
- "indeterminate," meaning that the test was inconclusive and additional testing may be required.[8]

26. If the HCV antibody test is positive, a second test, generally called an antigen test (HCVcAg) or RNA test, is needed to confirm the presence of active infection in the blood. As discussed *supra* at ¶13, approximately 25-30% of people who are infected with HCV will clear the infection without medical intervention. Individuals who have naturally cleared HCV or have successfully been treated for HCV will test positive for the HCV antibody, even though they are not actively or chronically infected. Patients who are HCV RNA positive have an active HCV infection. Patients who are HCV RNA negative, but who had a positive HCV antibody test, were either infected and eradicated the infection from their body, were successfully treated for HCV and cured with antiviral medication, or, less commonly, are actively undergoing HCV treatment and the virus is either suppressed or possibly eradicated.

[8] A false negative or indeterminate test result may occur when the individual was only recently infected with HCV, or another medical condition is impairing the individual's immune response. False negatives or indeterminate test results arise only in unusual circumstances, and are relatively rare.

III. HISTORICAL TREATMENT OF HEPATITIS: THE MINNESOTA DEPARTMENT OF CORRECTIONS BECOMES ONE OF THE FIRST STATE CORRECTIONS DEPARTMENTS TO DEVELOP AND IMPLEMENT HEPATITIS C TREATMENT GUIDELINES.

27. In 1999, CMS was the DOC's contractor. CMS would not treat inmates for HCV. I went to the DOC's administration and advocated that the DOC should treat inmates with HCV.

28. In April 1999, the DOC put together an advisory committee to make recommendations regarding HCV screening, treatment, education, and prevention for Minnesota's prisoners. The committee issued its Report to the Commissioner in September 1999. The committee developed guidelines for treating HCV, which I believe were among the first guidelines for HCV treatment in U.S. prisons. The DOC committed to treating inmates who have HCV and has retained that commitment. The DOC voluntarily shared the cost of HCV treatment with CMS.

29. The committee discussed eligibility criteria based on inmate-specific clinical presentation of the virus and liver disease, the anticipated length of treatment and anticipated release date, and any public safety or behavioral concerns.

30. At that time, the combination therapy of interferon and ribavirin was being used to treat individuals with HCV. Interferon is a protein made by the body and is used to fight off various pathogens, including viruses, by interfering with viral replication. Interferon can also be manufactured. Ribavirin, a separate prescription drug, was another component of interferon treatment regimen at this time. The dosing at the time required

interferon injections three times per week. The DOC treated inmates with interferon and ribavirin.

31. In 2002, the FDA approved pegylated interferon (trade name Pegasys or PEG-Intron), for treatment of HCV and Hepatitis B. Pegylated interferon is a manufactured formulation which attaches polyethylene glycol to interferon, which studies show resulted in slowing of the body's process of releasing the interferon into the blood. This reduced the number of injections to once per week, reduced the side effects of the injection and improved outcomes. This slowing resulted in more efficient and effective treatment of HCV. In patients with HCV, administration of pegylated interferon protects healthy cells from the virus, interferes with replication of the virus, and aids the body in eliminating infected cells. Ribavirin significantly reduced the rate of relapse and improved the rate of sustained virologic response when compared to treatment with pegylated interferon alone. Pegylated interferon required an injection only one time per week. After the approval of pegylated interferon, practitioners used a combination therapy of pegylated interferon and ribavirin with greater effectiveness than previous treatments utilizing only interferon. The DOC treated inmates with interferon and ribavirin until the FDA approved a more effective treatment regimen.

32. The DOC's HCV treatment guidelines changed over time, largely in response to medical developments, including the availability of new medications or treatment regimes, but underlying eligibility and treatment criteria were largely carried forward.

33. The initial committee made recommendations regarding drug and alcohol use that were carried through in the HCV treatment guidelines until January 2016.[9] Some members of the advisory committee came from a public health background. Committee members found it appropriate to encourage inmates to complete chemical dependency (CD) treatment, both as a means to provide for the whole health of each inmate but also because many HCV-infected persons acquired the virus outside of prison as a result of intravenous drug use. The risk of a person becoming re-infected with HCV was high if the person was chemically dependent and had not been treated for his or her chemical dependency. Additionally, unlike many viral infections prior infection does not provide an individual immunity from future HCV infection.

34. Inmates receiving HCV treatment in prison were obviously prohibited from consuming alcohol or using non-prescribed drugs while incarcerated. They were also obviously prohibited from doing so during the treatment regime and were subject to random drug testing during treatment. This was to encourage the long-term success of the treatment and also to avoid complications that could arise from concurrent drug use during treatment.

35. Many people who have HCV acquired it through intravenous drug use. Even if antiviral treatment is successful in the short term, it is likely to be unsuccessful in the long term if a chemically dependent patient refuses to complete CD treatment. I

[9] Despite the good public policy reasons for the CD treatment requirement, as well as that it represented a multi-disciplinary approach to inmate healthcare and wellbeing, the CD requirement was discontinued with adoption of the 2016 Guidelines and has not been reintroduced as a requirement in any subsequent versions of the DOC's Guidelines.

believe that, at the time, other entities, such as insurance companies, were requiring CD treatment or a period of abstinence for patients receiving treatment with HCV medication. It is my understanding that these requirements are still in place.

36. When the DOC required CD treatment as part of the guidelines, it could be waived by me at any time. I reviewed each inmate's situation on a case-by-case basis and waived the CD requirement where medically appropriate or for practical reasons. For instance, I would waive the CD treatment requirement if an inmate was physically unable to attend treatment because of his or her security status or if the inmate had an immediate medical need.

37. Based on the availability of new medications and changing approaches to HCV treatment based on genotype, the DOC amended the guidelines in 2002, 2003, 2006, and 2007. As of 2007, the recommended treatment was a 48-week course of pegylated interferon and ribavirin.

38. In approximately May 2011, the FDA approved telaprevir for treatment of HCV genotype 1. Its trade name was Incivek. In approximately May 2011, the FDA also approved boceprevir for treatment of HCV genotype 1. Its trade name was Victrelis. Telaprevir and boceprevir were both protease inhibitors, and the earliest DAAs approved by the FDA.

39. Each of these new medications needed to be used in combination with pegylated interferon and ribavirin. They had complicated and frequent dosing regimens, and had significant and common side effects. Inmates receiving the medications required close monitoring and frequent laboratory testing. These requirements made

administration difficult in a prison setting; however, inmates were treated with both medications. The HCV treatment guidelines were revised in August 2012 to provide treatment either with pegylated interferon, ribavirin, and a protease inhibitor (with preference to boceprevir) or with pegylated interferon and ribavirin, depending on the inmate's genotype.

IV. DIRECT-ACTING ANTIVIRALS AND THE DOC'S EVOLVING TREATMENT OF HEPATITIS C.

40. Current treatments for HCV belong to a class of drugs known as DAAs, and the current batch of drugs began with the approval of Olysio (simeprevir) in late November 2013. Olysio works by blocking a protein needed by the Hepatitis C virus to replicate, and was prescribed for use in combination with pegylated interferon and ribavirin. Olysio is still available, but is not in common use because it had to be combined with other medications to be effective.

41. Shortly after the approval of Olysio, the FDA approved Sovaldi (sofosbuvir) in December 2013. Like Olysio, Sovaldi blocks a specific protein needed by the Hepatitis C virus to replicate. While DAAs have significantly changed the way the medical community treats HCV, they are oftentimes not as simple as just giving a patient one pill one time every day. For instance, depending on genotype, Sovaldi can be used in combination with pegylated interferon and ribavirin or just ribavirin. The treatment course could be 12-24 weeks, depending on genotype. Like Olysio, Sovaldi is still available but is not frequently used because it cannot be used alone, and must be used in

combination with another drug. The DOC first treated an inmate with a combination of Sovaldi, pegylated interferon, and ribavirin in 2014.

42. Since the approvals of Olysio and Sovaldi, multiple drugs were approved by the FDA for treatment of HCV that are based on essentially the same underlying science. Treatment of HCV has been revolutionized over the last several years. Harvoni (a combination of sofosbuvir, the same drug as Sovaldi, and ledipasvir) was approved by the FDA in late 2014 for treatment of genotype 1 patients. Unlike Olysio and Sovaldi, Harvoni is itself a combination of two medications and does not need to be used in combination with another medication. Like Harvoni, subsequent medications include multiple medications in one pill. The DOC first treated an inmate with Harvoni in 2015. Viekira Pak (a combination of ombitasvir, paritaprevir, ritonavir, and dasabuvir to be used with or without ribavirin) was approved by the FDA in late 2014. The DOC first treated an inmate with Viekira Pak in 2015. Zepatier (elbasvir andgrazoprevir) was approved by the FDA in January 2016. The DOC first treated an inmate with Zepatier in 2016. Epclusa (sofosbuvir and velpatasvir), a pangenotypic drug, was approved for treatment of all genotypes in June 2016. The DOC first treated an inmate with Epclusa in 2016. Mavyret (glecaprevir and pibrentasvir) was approved by the FDA in August 2017. The DOC first treated an inmate with Mavyret in 2017.

43. As the DOC's Medical Director, I stay abreast of medical literature. I also regularly interact with medical personnel from other prison systems and medical personnel who work for the DOC's medical contractor. I have revised the DOC guidelines for HCV treatment in light of these new medications and subsequent

developments in how corrections systems across the United States treat inmates with HCV.

44. On April 8, 2015, the DOC issued revised HCV treatment guidelines (hereinafter "2015 Guidelines"). Attached hereto as Exhibit B is a true and correct copy of the 2015 Guidelines.

45. In drafting the DOC's 2015 guidelines, I considered medical literature indicating that approximately 75% of those who get infected with HCV become chronic carriers and approximately 25% clear the virus from their systems and do not have a chronic infection. I also considered that liver disease progresses slowly, and that for chronically infected persons, only a small portion develop significant liver disease even after many years. I also considered that the disease progresses more slowly in Minnesota prisons than outside prison because consumption of alcohol is forbidden and, even if inmates break the rules, consumption of alcohol would be very limited in prison as compared to the community.

46. At the time I drafted the DOC's 2015 Guidelines, the medical and correctional medical communities were utilizing FIB-4 and APRI scores to prioritize treatment with DAAs. Some were using one or both. I was using both the FIB-4 and APRI scores. Although I continue to review FIB-4 and APRI scores, I now use the scores to prioritize inmates to receive ultrasound elastography as the DOC's preferred method of staging liver disease.

47. Because many inmates' prison sentences were too short to accommodate the pre-treatment evaluation, the 48-week treatment regime, and the six-month

aftercare/monitoring period, many inmates did not participate in HCV treatment prior to the release of current DAAs. Many other inmates serving longer sentences decided not to pursue treatment because they thought the side effects and toxicity outweighed the potential benefits when the treatment may not be successful in eradicating the virus. With the availability of new medications, which had a much shorter treatment period, less side effects, and greater success rate, I anticipated that there would be a significant increase in demand for treatment with HCV medications. Thus, in drafting the April 2015 Guidelines I considered how other practitioners were addressing the provision of the new medications, including practitioners in correctional/institutional settings.

48. I consulted the June 2014 Interim Guidance for Management of Chronic Hepatitis C Infection (hereinafter "FBOP Interim Guidance") in drafting the DOC's April 2015 Guidelines published by the Federal Bureau of Prisons (FBOP). The FBOP administers the federal prison system and its treatment guidelines, including those for treatment of HCV, are used in many states as a guidepost for setting standards for health care provided by state correctional systems. A copy of the FBOP's Interim Guidance is attached as Exhibit C.

49. The FBOP's Interim Guidance noted that the new DAA medications had been introduced for treatment of HCV and more were expected to be introduced, "resulting in rapidly changing clinical guidelines and treatment recommendations." FBOP Interim Guidance at 1. The FBOP stated that, "[d]uring this time of transition, the FBOP has established treatment priorities for inmates who have a more urgent need for intervention . . . ." *Id.* The FBOP prioritized treatment for inmates with advanced

fibrosis/cirrhosis; liver transplant recipients; HIV co-infection; and comorbid medical conditions associated with HCV, such as cryglobulinemia and some types of lymphomas. *Id*. The FBOP also recommended continuing to provide medication to inmates who had been on the medication when they entered prison on the medication. *Id*.

50. In its interim guidance, the FBOP noted that APRI scores correlate fairly well with more advanced fibrosis/cirrhosis. As such, the FBOP prioritized treatment for inmates who have an APRI score of 1.0 or more, or who have a score of between 0.7 and 1.0 along with other findings suggestive of advanced fibrosis such as low albumin or platelets, elevated bilirubin or INR. *Id*.

51. The American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) have issued guidance for the treatment of HCV. This guidance is periodically updated and the AASLD/IDSA have characterized the guidance as a "living document." The AASLD/IDSA guidance does not establish a medical standard of care, but rather provides treatment options based on genotype, subtype, previous treatment history, degree of liver fibrosis, and other clinical issues as an organized and inclusive reference. The aspirational public health statements included in the AASLD/IDSA's publications do not define a medical standard of care. In drafting the DOC's 2015 Guidelines, I also consulted the AASLD/IDSA's December 2014 recommendations. A true and correct copy of an excerpt of the AASLD/IDSA recommendations from December 2014 ("Dec. 2014 AASLD/IDSA") is attached hereto as Exhibit D.

52. The December 2014 AASLD/IDSA recommendations noted that subjects who are cured of their HCV infection experience health benefits including a decrease in liver inflammation and a reduction in the rate or progression of liver fibrosis. The guidance provided that "[t]reatment is recommended for patients with chronic HCV infection." Dec. 2014 AASLD/IDSA at 2. The December 2014 recommendations also noted that "urgent initiation of treatment is recommended for some patients, such as those with advanced liver fibrosis or compensated cirrhosis." *Id.* at 3. The recommendations stated:

> Immediate treatment is assigned the highest priority for those patients with advanced fibrosis (Metavir F3), those with compensated cirrhosis (Metavir F4), liver transplant recipients, and patients with severe extrahepatic hepatitis C (Table 1).
>
> Based on available resources, immediate treatment should be prioritized as necessary so that patients at high risk for liver-related complications and severe extrahepatic hepatitis C complications are given high priority (Table 1).
>
> The most immediate and high-impact benefits of [sustained viral response] will be realized by populations that are at the highest risk for liver-related complications due to progressive liver disease (Metavir F3 or F4) and transplant recipients or those with clinically severe extrahepatic manifestations (Table 1).
>
> Other populations at high risk for liver disease progression (Metavir F2) or with substantial extrahepatic manifestations (Table 1) are also expected to garner appreciable benefits, although the time course for realizing these benefits may be more protracted.

Id. at 3.

53. I also consulted Centurion's guidelines. A true and accurate copy of Centurion Disease Management Guidelines, HCV-Infected Patients, is attached as Exhibit E. The guidelines were issued on December 15, 2014 and indicated they would

be effective on March 1, 2015. *Id.* at 1. Centurion's guidelines provide that APRI and FIB-4 scores should be calculated for a subject with HCV. *Id.* at 2. The guidelines provide that subjects with stage 3 fibrosis or higher should be the highest priority for treatment. *Id*. at 3. The guidelines provide that subjects with a APRI score of 2.0 or greater, or a FIB-4 score of greater than 3.25, do not usually need further confirmation of their fibrosis stage by elastography or liver biopsy. *Id.* The Centurion guidelines provided that, at the time, treatment of subjects with stage 2 fibrosis was not recommended, with exceptions for subjects with HIV infection or other diseases where evidence indicates that progression of hepatic fibrosis is inevitable and controlling hepatic fibrosis will assist in controlling other underlying diseases. *Id.* Centurion's guidelines indicate that subjects were not eligible for HCV treatment unless they had been clean and sober for at least twelve months prior to starting treatments. *Id*. at 2.

54. I consulted other sources, including UpToDate, a subscription-based medical resource that is peer-reviewed and evidence-based, my colleagues in correctional medicine, and information I learned attending the National Commission on Correctional Health Care (NCCHC) national conference. I also consulted the 2014 guidelines for HCV treatment from the California Department of Corrections.

55. Based upon my review of the then-available medical literature and other sources, I drafted the DOC's 2015 Guidelines with an object of prioritizing HCV treatment for persons with the greatest need. The first priority was stage 4 (compensated cirrhosis), followed by stage 3 (moderate fibrosis), followed by inmates with stage 2 fibrosis and several other medical conditions (i.e., HBV, HIV, or diabetes with insulin

resistance). The 2015 Guidelines noted that, if resources permit, the DOC would offer treatment to other inmates at a lesser risk for complications. The 2015 Guidelines were in accord with recommendations by the FBOP and other entities making treatment decisions for prisoners or other institutionalized populations. It is also my understanding that insurance companies were doing the same evaluation of their insureds' medical condition before approving treatment.

56. In 2016, I drafted and approved the Minnesota Department of Corrections' Guidelines for Evaluation and Management of Chronic Hepatitis C (HCV) Infection (hereinafter "the 2016 Guidelines") after considering a wide variety of sources including the Clinical Practice Guidelines adopted by the FBOP, the guidelines in use in other states such as California, and the AASLD/IDSA guidance that was then in effect. Attached hereto as Exhibit F is a true and correct copy of the 2016 Guidelines. When the 2016 Guidelines were adopted, they mirrored the FBOP Clinical Practice Guidelines.

57. I executed a previous Affidavit in this matter dated March 28, 2017. (Doc. 108 (version filed under seal); Doc. 109 (publicly-filed version)). At that time, the DOC had treated with DAAs all consenting F3 and F4 inmates who had been identified by the DOC as having chronic HCV. The DOC had also treated with DAAs all consenting inmates with F2 and certain comorbid conditions as identified in the 2016 Guidelines. Other inmates outside of these groups received treatment in my medical judgment (e.g., inmates who were admitted to the custody of the DOC on DAAs). At that time, the DOC was beginning to identify for treatment F2 inmates who had been deferred for treatment because they did not have an immediate medical need for such treatment.

58. Thereafter, I drafted the DOC's Guidelines for Evaluation and Management of Chronic Hepatitis C (HCV) Infection in September 2017 (hereinafter "2017 Guidelines"). Attached hereto as Exhibit G is a true and correct copy of the 2017 Guidelines. The 2017 Guidelines expanded treatment to all prisoners with stage 2 fibrosis as well as those with stage 1 fibrosis and certain comorbid conditions.

59. At the time the 2017 Guidelines were drafted and adopted, the AASLD/IDSA recommendations did not identify any immediate adverse medical consequences of prioritizing treatment for those with advanced liver disease. Just as it does now, the AASLD/IDSA noted that "in certain settings there remain factors that impact access to medications and the ability to deliver them to patients. In these settings, practitioners may still need to decide which patients should be treated first." *Id.* at 2. Attached hereto as Exhibit H is a true and correct copy of an excerpt from the recommendations currently posted on the AASLD's website. It contains the same language recognizing that prioritization may be appropriate.

V. THE DOC'S CURRENT SCREENING AND TREATMENT GUIDELINES.

60. On April 16, 2018, the DOC implemented revised "Guidelines for Evaluation and Management of Chronic Hepatitis C (HCV) Infection" (hereinafter "2018 Guidelines"). Attached hereto as Exhibit I is a true and correct copy of the 2018 Guidelines. Just like the 2017 Guidelines, the 2018 Guidelines were drafted and approved after I consulted a variety of sources, including: the FBOP's Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection Clinical Guidance from May 2017; medical literature discussing the treatment of patients with HCV and certain other

medical conditions, such as diabetes, fatty liver, and hepatocellular carcinoma; pertinent sections of UpToDate; the Chronic Hepatitis C Evaluation and Treatment: 2017 Clinical Practice Guidelines for the Oregon Department of Corrections (ODOC); the Massachusetts Department of Correction Clinical Guidance for the Evaluation and Management of Chronic Hepatitis C (HCV) Infection from February 2018; the Minnesota Department of Human Services' policies and procedures for health care programs' treatment of HCV with DAAs from November 2017; and the California Correctional Health Care Services' Care Guide for Hepatitis C from December 2017. As always, my years of experience as a medical doctor and experience in correctional health care also informed the 2018 Guidelines. A true and correct copy of the FBOP clinical guidance is attached hereto as Exhibit J. A true and correct copy of the Oregon guidelines is attached hereto as Exhibit K. A true and correct copy of the California care guide is attached hereto as Exhibit L.

61. The AASLD/IDSA recommendations continue to recognize that certain settings require prioritization. The recommendations do not identify any long-lasting adverse health consequences for stable patients who are deferred for reassessment.

62. The federal Centers for Disease Control (CDC) has never promulgated any guidelines for treatment of HCV.

63. The DOC's 2018 Guidelines are not a policy, and are meant only to provide general guidance to medical staff and inmates regarding the DOC's current plan to treat HCV-infected inmates in a fast-changing environment. The Guidelines are not meant as a substitute for medical judgment exercised on the basis of each inmate's unique medical

circumstances, which is recognized on the bottom of each page of the 2018 Guidelines. The 2018 Guidelines establish a general process for review of each HCV-positive inmate's specific medical condition and medical needs, including the stage of liver disease, if any, and any comorbid conditions that would be otherwise medically significant.

64. I take steps to stay abreast of how other correctional systems are handling HCV treatment. I do not know of any state departments of corrections that are treating all HCV-positive inmates. Rather, all of the state departments of corrections I am aware of that are treating inmates with DAAs prioritize treatment as does the FBOP.

65. The 2018 Guidelines expand the DOC's approach to treating HCV with DAAs by increasing the inmates who are considered for immediate treatment and by changing the DOC's opt-in HCV testing process to an opt-out process. Although opt-in testing for HCV resulted in the vast majority of new inmates being tested for HCV at the DOC's intake facilities, I decided to revise the 2017 Guidelines and implement the 2018 Guidelines. This decision was based on my understanding that the FBOP and the Massachusetts Department of Corrections had both switched from opt-in to opt-out testing. I also learned that the CDC was internally reviewing whether to change its testing recommendation from opt-in to opt-out testing for HCV. I decided to add diabetes and steatohepatitis to the lists of comorbid conditions based on recent medical literature. For instance, recent literature preliminarily concludes that treating HCV allows better diabetic control and may delay progression of kidney disease in people with diabetes and HCV. The changes in treatment considerations have already been

implemented in my review of HCV cases. The change from opt-in testing to opt-out testing will require DOC staff to be trained at the intake facilities. I have instructed Health Services staff at the intake facilities to immediately begin opt-out testing.

66. As with the 2016 and 2017 iterations of the Guidelines, the 2018 Guidelines do not name specific drugs because new drugs are still being developed and approved by the FDA. Because the DOC and I were aware that there would continue to be rapid changes in the available drugs to treat HCV, the 2015 Guidelines and all subsequent versions of the Guidelines were drafted to provide general guidance but not to be too specific. The 2018 Guidelines were drafted to provide general guidance to medical personnel as those changes occurred. In selecting an HCV medication for a particular inmate, I utilize the treatment guidance published by the AASLD/IDSA to determine which treatment regimen best fits the inmate based on his or her genotype, lab results, and other medical factors.

A. Testing For Hepatitis C At The DOC.

67. The 2018 Guidelines establish an opt-out testing procedure for inmates at intake. Opt-out testing means performing a test after informing the patient that the test will be performed, but that the patient may either decline testing or defer testing. The DOC's testing of new inmates for HCV begins when they arrive at the DOC's intake facilities at the Minnesota Correctional Facility in St. Cloud (MCF-SCL), the intake facility for adult males, the Minnesota Correctional Facility in Shakopee (MCF-SHK), the only DOC facility for adult females, and the Minnesota Correctional Facility in Red Wing (MCF-RW), the DOC facility that performs intake on juvenile males.

68. Under the 2018 Guidelines, DOC staff members explain the risk factors, as identified by the CDC, for HCV to inmates. The risk factors, as identified by the CDC, and communicated to inmates during the intake assessment, include: 1) history of injection drug use; 2) tattoos or body piercings from an unlicensed provider; 3) having HIV or AIDS, and 4) being born between 1945 and 1965. I have heard prison discussed as a risk factor for HCV; however, being in prison is not in and of itself a risk factor. Listing prison as a risk factor stems from the fact that individuals who have been in prison are disproportionately more likely to have engaged in activities that are otherwise a risk factor for transmission of HCV (i.e., injection drug use or tattooing or piercings in an unlicensed facility). Moreover, there is no evidence within the Minnesota DOC of inmates transmitting HCV or other bloodborne diseases to one another within the prison setting. While other states or countries may experience frequent inmate-to-inmate transmission of HCV, there is no evidence of HCV any transmission in Minnesota prisons, let alone the rates of transmission sometimes identified in medical literature.

69. DOC staff members have also been instructed and are expected to educate and provide written information to inmates regarding transmission, and potential impact of chronic HCV infection, what HCV testing involves, and how chronic HCV infection is managed and treated.

70. Inmates who are tested for HCV either at intake or who request testing during their incarceration receive the tests that are part of the two-step process identified to determine whether an inmate has HCV. First, medical staff at the correctional facility draw two tubes of blood from the inmate. The two blood samples are then sent to

BioReference Laboratories for testing. BioReference Laboratories is Centurion's contracted laboratory facility for non-emergency tests that cannot be run in the correctional facility. If the inmate's first blood sample tests positive for the HCV antibody, the second blood sample is tested for the HCV antigen. If the first sample tests negative, then the second sample is destroyed and no further testing is performed. If the first sample tests "inconclusive," the test is repeated at an interval determined by the practitioner ordering the test. Inmates who test positive for the HCV antigen (HCV RNA positive) undergo both an initial evaluation and periodic monitoring.

71. During intake, DOC staff members have also been instructed and are expected to explain the procedures an inmate should follow to request HCV testing after the intake screening and testing. After intake, an inmate can request an HCV blood test or such test can be ordered by a medical practitioner. Inmates who request HCV blood testing are not charged a copay and are not required to disclose the presence of any risk factor(s) (i.e., an inmate requesting a test is not required to explain that he or she engaged in illicit activity while in the custody of the DOC). When inmates report exposure to a bloodborne pathogen, they are also provided with the option of a test for HCV and other bloodborne pathogens.

72. I do not recall ever receiving any kites or grievances from an inmate stating that he or she had requested an HCV test, but was not given the test by his or her practitioner.

B. Monitoring of HCV-Infected Inmates At The DOC And Initiation Of Treatment.

73. Inmates whose HCV antigen/RNA test show that they have chronic HCV infection are scheduled for an initial evaluation with an on-site medical practitioner. During the initial evaluation, the on-site medical practitioner explains the test results to the inmate. The steps for these initial and periodic follow-up examinations are included in the 2018 Guidelines, and it is my expectation that the medical practitioners at each facility follow the 2018 Guidelines. The 2018 Guidelines state that during the initial evaluation practitioners will conduct an initial evaluation that includes:

- A targeted history and physical exam
- Laboratory tests including: (these may be done prior to the visit)
    - Complete blood count (CBC)
    - Complete metabolic profile (CMP)
    - International normalized ratio (INR)
    - HIV antigen/antibody test
    - Hepatitis B surface antigen, surface antibody and hepatitis B core antibody
    - Hepatitis A antibody
    - Additional tests that the practitioner determines are indicated;
    - HCV genotype test may be delayed until antiviral treatment is planned;
- Immunizations for hepatitis A and B if indicated;
- Order Pneumococcal vaccine, if there is evidence of cirrhosis.

- Explanation to the inmate about the process for periodic evaluation and criteria for determining treatment eligibility; and
- Providing the offender with recommendation for frequency of follow-up.

74. This initial evaluation sets the baseline for subsequent evaluations. Pursuant to the 2018 Guidelines, HCV-positive inmates are given written instructions about how frequently they should schedule periodic follow-up evaluations. Currently, inmates are told to follow up every six months. The practitioner may recommend more frequent follow-up. Inmates are also informed that HCV follow-up evaluations are free and do not require a copay. It is incumbent on inmates to schedule and attend follow-up appointments, unless the inmate has been identified as one who is incapable of managing this aspect of his or her healthcare. [redacted]

75. I have directed the practitioners to complete and forward to me a form entitled "Hepatitis C New Case and Case Follow-up Report," so that I can track the inmate's medical status at the DOC Central Office. A true and correct copy of the Hepatitis C New Case and Case Follow-up Report is attached hereto as Exhibit M (hereinafter "Hepatitis C Case Report"). The Hepatitis C Case Report is to be completed both after the initial evaluation and after any follow-up evaluations. The Hepatitis C Case Report contains all of the information relevant to my review of each inmate's

medical status. Both during training and periodic meetings with the practitioners I have repeatedly stressed that each medical practitioner should emphasize with HCV-infected inmates the importance of following up about HCV. I have also emphasized during training and periodic meetings that each practitioner must keep me updated with any developments with regards to inmates with active HCV infections.

76. Once the initial assessment is completed, the Hepatitis C Case Report arrives at the DOC Central Office, a DOC staff member uses the information contained on the report to complete another form, entitled the Hepatitis C Evaluation and Treatment Patient Review Form (HCV Patient Review Form), for my review. A true and correct copy of the HCV Patient Review Form is attached hereto as Exhibit N. This version of the HCV Patient Review Form was used beginning April 16, 2018. The HCV Patient Review Form includes information relevant to my consideration of each HCV-positive inmate's medical status.[10]

77. Once the HCV Patient Review Form is completed, both the Hepatitis C Case Report and the HCV Patient Review Form are provided to me for my review. I then evaluate all of the clinical information included therein to determine the inmate's priority for ultrasound elastography, if it has not already been performed.

78. In early spring of 2017, the DOC requested that Centurion, its contracted medical provider, provide ultrasound elastography technology for use in the DOC's facilities. Thereafter, the DOC and Centurion worked with Professional Portable X-Ray

[10] Some inmates report on intake having received such testing outside of the DOC but do not have records indicating test results.

("PPX"), Centurion's contracted imaging provider, to identify the technology to be purchased by PPX and used in DOC facilities. Through Centurion and PPX, the DOC began staging of liver disease using a GE LOGIQ E9 Shear Wave Elastography system in early July 2017. The tests provided to each inmate who consents are: (1) ultrasound-based liver elastography and (2) a limited abdominal ultrasound. The results of these procedures are reviewed and interpreted by a radiologist. The radiologist's report is forwarded to the inmate's facility for review by the on-site practitioner and for entry into the inmate's medical record. PPX also sends the results to me at the DOC's Central Office. Elastography provides a stage (stages 0 through 4). In combination, the elastography and limited abdominal ultrasound can detect other liver conditions such as liver masses and infection.

79. Ultrasound elastography is prioritized based on APRI and FIB-4 calculations. I anticipate that all current inmates on the elastography prioritization list, and who consent to the procedure, will have had an initial elastography exam by the end of June 2018.

80. Based on all medically relevant information, including but not limited to each inmate's ultrasound elastography results and other clinically-relevant information, I determine whether each inmate with HCV should receive immediate treatment with DAAs or receive further monitoring, testing, or evaluation. Under the 2018 Guidelines individuals with an immediate medical need for treatment and others who have demonstrated that they may benefit from immediate treatment receive immediate treatment with DAAs.

81. If an inmate is identified as a having an immediate need for treatment based on his or her medical condition, I order any additional testing and take all other steps necessary to have on-site practitioners start treatment.

82. With the exception of those inmates identified who are unable to seek follow-up care on their own behalf, it is then incumbent on the inmate to schedule and attend the follow-up evaluations every six months as recommended. It is incumbent on the on-site medical practitioner to keep me informed of any changes in the inmate's medical condition that would be clinically significant in my assessment of the inmate's priority for treatment. Like the initial evaluation, all follow-up evaluations are conducted by medical practitioners in the prison where the inmate is located. During each follow-up appointment, a lab technician on-site draws blood samples for testing. These tests are used to monitor the inmate's liver function and determine whether the inmate has any evidence of progressing liver disease. As explained by the 2018 Guidelines, practitioners are expected to perform, at a minimum, the following evaluation at each HCV follow-up appointment:

- an interim targeted history and physical examination;
- order lab testing, including a CBC, CMP, and INR; and
- order any other testing that is clinically indicated, including repeat liver elastography as indicated in the 2018 Guidelines.

83. Following my review of the initial reports, I expect to be updated on each HCV-positive inmate's status by the on-site medical practitioner who sees the inmate after each follow-up appointment. Outside of these periodic follow-up appointments, I

also expect to be informed of relevant changes in the inmate's health that could either medically impact the inmate's HCV or liver disease. I have informed the on-site practitioners of these expectations, and have directed them to complete the same Hepatitis C Case Report after each follow-up appointment. As with the Hepatitis C Case Report completed after an inmate's initial evaluation, I have instructed the on-site medical practitioners and nursing staff at all DOC prisons to forward the completed report to the DOC's Central Office. The updated information is again transcribed from the Hepatitis C Case Report to the HCV Patient Review Form, and both forms are provided to me for my review. As with my review of each inmate's medical condition following his or her initial HCV evaluation, I use both the Hepatitis C Case Report and the HCV Patient Review Form to track each HCV-positive inmate's medical status following each follow-up evaluation.

84. Generally, a patient with HCV can be monitored for the effects of the disease and any changes in medical condition through blood tests and staging, such as elastography. HCV and liver disease progress very slowly, if at all. In most cases it takes decades to progress. The routine follow-up visits detailed above include blood testing allow the practitioner at the facility to calculate FIB-4 and APRI scores. If one of the on-site medical practitioners identified something of concern either on the Hepatitis C Case Report or in a conversation with me, such as a comorbid condition or symptom requiring attention, it is my expectation that such condition or symptom be addressed as medically appropriate by that on-site medical practitioner. I also expect the on-site medical practitioner to bring any such condition to my attention if it would be clinically

significant in my assessment of the inmate's need for immediate HCV treatment. I have informed Centurion medical practitioners that I am available to discuss the process or individual cases and have encouraged them to do so.

85. In addition to an inmate's elastography results and FIB-4 and APRI scores, I also review any other relevant test or procedure results that would be relevant to my assessment of the inmate's medical condition before making a decision as to treatment priority as previously described. If I need additional information or have questions, I can review the inmate's laboratory results and current medical treatment online, previous Hepatitis C Case Reports, which I maintain in my office, a list of the inmate's current medications online, previous information from a database of HCV-infected inmates, or other records sent to me by an on-site medical practitioner. I do not have access to other portions of an inmate's medical record in my office. In some cases, I contact the on-site medical practitioner or an on-site nurse for additional information (i.e., medical records that are maintained on site and not available electronically). I can, and have in a number of instances, request additional testing, including HIV, genotyping, alpha fetoprotein screening, liver or abdominal ultrasound, an abdominal MRI or CT, ultrasound elastography, FibroSure panel, NS5a test, and INR.

86. Based on the case reports and any other relevant clinical information, I use my medical judgment to assess each inmate's medical condition. I evaluate this information to determine whether the inmate should receive immediate treatment with FDA-approved DAAs or to defer treatment. I make this decision each time additional information comes to me from the on-site providers. An individual's need for medical

treatment is based on his or her own unique medical condition. The treatment options for HCV have changed significantly over time.

87. Because individuals can be reliably monitored with the use of ultrasound elastography, blood tests and other procedures when medically appropriate, the DOC has prioritized certain inmates HCV for immediate treatment. Under the 2018 Guidelines, priority treatment (i.e., immediate treatment) is given to inmates who have advanced fibrosis (stage 3 or stage 4), mild fibrosis (stage 2), and other inmates who have:

- concurrent Hepatitis B infection (HBV);
- human immunodeficiency virus (HIV);
- certain comorbid conditions such as cryoglobulinemia;
- received a liver transplant;
- hepatocellular carcinoma;
- certain other malignancies, such as such B-cell lymphoma or other hematologic malignancies;
- steatohepatitis;[11]
- renal insufficiency;[12] and
- diabetes mellitus.[13]

An inmate is generally only provided treatment with DAAs if sufficient time remains on his or her sentence to complete the course of treatment.

[11] *See* Appendix ¶ DDD (defining steatohepatitis).
[12] *See* Appendix ¶ UU (defining renal insufficiency).
[13] *See* Appendix ¶ L (defining diabetes mellitus).

88. The DOC prioritizes treatment for those who, in my medical judgment and based on their test results, are either in need of immediate treatment or who may medically benefit from treatment. As previously explained, the 2018 Guidelines prioritize treatment based on the inmate's stage of liver disease or the presence of a comorbidity. The DOC's practice meets or exceeds the clinical practice guidelines currently in effect at the FBOP.

89. In determining which inmates should receive immediate treatment, I review each inmate's medical history and information reported to me through periodic follow-up appointments with the Centurion medical providers. I consult the current DOC Guidelines but make an independent decision with regard to each inmate based upon the particular facts and circumstances and the most current information available to me, including the inmate-specific medical information made available to me by the on-site medical practitioners.

90. As medical director of the DOC, I must take a population-based approach to the medical care provided to inmates. In this environment, the DOC must treat a wide variety of inmates for a wide variety of health issues, with a limited amount of human, structural, and monetary resources. In addition to treating inmates who have HCV, the DOC treats substantial numbers of inmates with chronic medical conditions like cancer, heart disease, diabetes, hypertension, prior stroke or brain injuries, arthritis, persistent asthma, HIV, severe mental illness, digestive disorders, and an aging prison population with substantial medical needs.

91. The DOC cannot treat all HCV-positive inmates at once, so it must prioritize treatment. However, because HCV is a slowly progressing disease, such prioritization does not pose an immediate medical risk (or even a foreseeable risk in the longer term) to inmates who do not receive immediate treatment. With routine monitoring as laid out in the Guidelines, inmates can be monitored for progressing liver disease. In the context of a slowly-progressing disease, which takes decades to *potentially* cause acute medical complications, it is medically appropriate to treat the inmates with the greatest need first.

92. I have only a vague understanding of the DOC's medical budget and I do not know the specifics. I have never been told that the care I approve is too expensive or must fall within a certain budget. I do not receive budget reports and am not aware of where medical spending is in relation to the budget. I am not permitted to attend budget meetings, and have no need to do so for my duties. I do not make medical decisions based upon cost alone.

93. There has been an evolving standard of care within the medical community with regard to HCV treatment. In the community, an insurance company often decides who gets treated. Many people with HCV do not have insurance. The percentage of people with private health insurance, such as Blue Cross Blue Shield, who have HCV would be small. If the patient is on Medical Assistance (MA) and the patient's treating doctor wrote a prescription for a DAA, then MA would not cover it. MA would require a specialist to order it, and the specialist would serve as the gatekeeper before insurance would agree to cover DAAs.

94. When I have identified an inmate as having a high priority for immediate treatment, I assess the information that I have, including genotype, viral load, disease stage, and inmate-specific factors such as other medical conditions (i.e., HIV, renal insufficiency), whether the inmate is treatment naïve (i.e., has never received previous treatment for HCV) or treatment experienced. If additional information is needed to make a preliminary drug selection, I ask the on-site medical practitioner to perform any follow-up testing necessary so that I can determine the appropriate treatment regimen, including the type of antiviral or combination of drugs, that are most appropriate for the inmate.

95. I consult the most updated AASLD/IDSA publication to determine the appropriate treatment regimen. Once I have made a preliminary drug selection, a pharmacist conducts a search of the drug database to determine whether the inmate has prescriptions for any drugs that will interact with the proposed treatment regimen. I collaborate with the on-site practitioner to resolve any drug interactions with the proposed course of treatment. Generally this process is not complicated because the drugs that have an interaction with a DAA can be exchanged for an alternative drug or the dosing schedule changed to ameliorate the interaction, or an alternate HCV treatment can be used.

96. Before treatment can begin, the inmate's prescription medications and over-the-counter drugs are reviewed for contraindications. For instance, an inmate who takes antacids or medications for acid reflux like H2-receptor antagonists or proton pump

inhibitors may significantly decrease the efficacy of the prescribed DAA, in some instances to the point of causing a treatment failure.

97. DAA treatment involves several critical laboratory tests during pretreatment, treatment, and post-treatment. Pretreatment laboratory tests assist in determining whether treatment is appropriate, establish a baseline, and what treatment is necessary.

Pretreatment tests include:

- a complete blood count (CBC), which evaluates white and red blood cells and platelets, which are important in assessing normal blood clotting. A CBC is performed to evaluate a patient's overall health and screens for a wide range of disorders, including anemia, infection, inflammation, bleeding disorders and leukemia;

- HCV quantitative viral load, which measures the amount of the virus in one milliliter of blood and expressed as International Units (IU/mL);

- basic metabolic panel (BMP), which is used to evaluate a patient's kidneys and provides information about the status of a patient's kidneys, electrolyte and acid/base balance, blood glucose, and calcium levels;

- liver profile, which includes results for:

    - ALT, *see* Appendix ¶ B;

    - AST, *see* Appendix ¶ E;

    - ALP, an enzyme related to the bile ducts of the liver, which is often increased when the bile ducts are blocked;

    - albumin, which protein made by the liver, which can be affected by liver and kidney function;

    - total protein (TP), which measures albumin and other proteins in the blood, including antibodies made by the immune system to fight off infections; and

- bilirubin, which detects the amount of bilirubin in the blood and liver

- HIV serology;

- international normalized ratio (INR), which is a calculation based on the results of a prothrombin time (PT) test, which is used to detect a bleeding disorder or excessive clotting disorder;

- alpha-fetoprotein test (AFP), which screens for various cancers in men and non-pregnant women; an AFP test is followed-up with an ultrasound if results are abnormal;

- a pregnancy test for females;

- a genotype test, which identifies the genotype of HCV an individual has and assists a practitioner assessing a patient for treatment identify the correct medication; and

- NS5a resistance testing, depending on the drug, which detects whether an individual has a mutation to the NS5a gene and is associated with resistance to the NS5a inhibitors that are included in certain DAAs.

98. Even though DAAs have fewer side effects than previous treatment regimens that are no longer used, trained medical staff must monitor treatment before, during, and after the patient starts taking the DAAs. During treatment, patients follow-up with on-site practitioners for additional testing, including testing during, at a minimum, the fifth and ninth weeks to see if the drugs are working. During the fifth week, a blood test determines the inmate's viral load. An inmate is also tested during the seventh week if the test taken during the fifth week indicates that the inmate has a positive viral load. Testing may indicate that treatment should be stopped. For example, test results may indicate that liver enzymes have increased greater than tenfold, that renal (kidney) function has worsened, or that a positive viral load is detected in a patient's blood during

the seventh week of treatment. A positive viral load during the seventh week of treatment indicates that treatment is not reducing the amount of virus in the blood. Treatment with Vikiera Pak, a DAA that is FDA-approved, requires additional special monitoring in patients with compensated cirrhosis, including direct and indirect bilirubin monitoring at least monthly. These tests help practitioners identify whether treatment should be stopped and whether the inmate is failing treatment, or whether the inmate is responding to the course of treatment.

99. Many medications, including DAAs, are strictly managed in prison. The DOC differentiates between direct observed therapy (DOT) and keep on person (KOP) medications. An inmate may take a KOP with him and take it without the supervision of a health professional. An inmate must take DOT medications at designated times under the supervision of designated staff. When an inmate is suspected of diverting or "cheeking" a medication, the doctor may discontinue some medications or order that future DOT medications be crushed. Unfortunately, even with DOT, inmates may still divert the pills by "cheeking" them or "palming" them and then may sell or trade the pills to other inmates.

100. At the DOC, DAAs, among a wide variety of other prescriptions, are always DOT medications. Inmates must receive DAAs from DOC medical staff, and cannot keep the medication in their cells. While most patients in a community setting are allowed to self-administer medication, the corrections setting is unique. The high value of the drugs poses a risk to the inmate of theft or violence if they remain in his or her possession. As such, inmates must receive DAAs from medical staff at their respective

facilities' designated location. The DOT offers nursing staff a daily opportunity to monitor the inmate for side effects and adherence to treatment. Adherence is critical to successful treatment. In addition, DOT offers the inmate a daily opportunity to report side effects or other concerns.

101. I have emphasized to on-site medical staff, including DOC nursing staff, that it is imperative that inmates take all doses as scheduled. When an inmate does not show up to receive a dose, nursing staff have been instructed to call the inmate up to the scheduled med pass, which is the time at which medications are dispensed to inmates. If an inmate refuses a dose or expresses concerns, I have directed nursing staff to bring the issue to the attention of an on-site medical practitioner for review and follow up.

102. I have authorized treatment with DAAs for all inmates of whom I am aware have F2, F3 and F4 liver disease for whom it is appropriate, as well as others who have certain comorbid conditions or are in unique circumstances.

VI. PLAINTIFFS RONALDO LIGONS, BRENT BUCHAN, AND LAWRENCE MAXCY.

103. I understand that Plaintiffs Ronaldo Ligons, Brent Buchan, and Lawrence Maxcy (collectively "Named Plaintiffs") have alleged in this lawsuit that they received inadequate treatment for their HCV while they were incarcerated in Minnesota correctional facilities.

104. I reviewed medical records for Named Plaintiffs before preparing this Affidavit, and I had reviewed their medical records previously as part of my duties at the DOC's Medical Director. I will summarize a portion of their medical histories that may

be relevant to this lawsuit. This is not an exhaustive medical history of any of the Named Plaintiffs.

105. With Named Plaintiffs, as with all DOC patients, I have relied, and continue to rely, on Centurion practitioners to send me any information that they conclude is relevant to each respective patient's HCV and medical care. Prior to this litigation, I had never reviewed any of Named Plaintiffs' entire medical file. Such files are not readily accessible to me in my role as Medical Director. I do not regularly review inmate medical records unless specifically asked to do so or an unusual situation requires me to do so, and I do not have direct access to inmates' complete medical records from the DOC's Central Office where I work.

106. While I have individually assessed the information sent to me by on-site medical practitioners regarding Named Plaintiffs, [redacted]

[redacted]

A. RONALDO LIGONS.

107. I have reviewed medical records for Ligons [redacted]

108. [redacted].

109. [redacted]

B. BRENT BUCHAN.

110. I have reviewed medical records for Brent Buchan. I have never examined Buchan, and prior to this litigation, I had not reviewed his medical records, with the exception of those sent to me by on-site medical practitioners.

111. [redacted]

112. [redacted]

113. [redacted].

114. [redacted].

115. [redacted].

[redacted]

116. [redacted].

117. [redacted]

118. [redacted].

119. [redacted]

120. [redacted]

121. [redacted]

[redacted]

[redacted]

C. LAWRENCE MAXCY.

122. I have reviewed medical records for Lawrence Maxcy. I have never examined Maxcy, and prior to this litigation, I had not reviewed his medical records, with the exception of those sent to me by on-site medical practitioners.

123. [redacted].

124. [redacted]

[redacted]

[redacted]

[redacted].

125. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

126. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted].

127. HIV and HCV are different viruses. HIV targets a particular part of a patient's immune system, causing a degradation of its ability to protect the person from a variety of potentially and immediately life-threatening complications, primarily infections. This degradation often occurs over a short timeframe, such as within a months or a few years. HIV treatment with medications, while not curative of HIV, restores the immune function and the person's ability to defend against these complications. HCV in contrast does not have immediate life threatening or altering complications in the near or intermediate term. It does not impair the person's ability to prevent infections. Although it can cause liver damage, this damage, when it occurs, is a gradual process typically taking decades to cause significant impairment in liver functions. Testing and monitoring over time as described in the DOC Guidelines will detect this damage in its early phases. Like HCV, HIV can be transmitted through infected blood. However, unlike HCV, HIV is commonly sexually transmitted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

David A. Paulson, M.D.
David A. Paulson, M.D.

Subscribed and sworn to before me
on the 18th day of April, 2018.

Jennie Lynn Kill
Notary Public
My Commission Expires January 31, 2021

APPENDIX A

MEDICAL AND CORRECTIONAL TERMS GLOSSARY

The following list of terms is included as a glossary for ease of reference for a selection of the medical and correctional terms used in this Affidavit:

A. **A1C:** A hemoglobin A1C test measures a patient's blood sugar over the preceding 2 to 3 months.

B. **ALT (or alanine aminotransferase):** An enzyme found in liver cells (hepatocytes) and used for detecting the presence of hepatitis (here meaning inflammation of the liver from any cause, not only a viral infection).

C. **Antibody:** A protein made by the body's immune system when it detects harmful substances, called antigens such as viruses, and bacteria.

D. **Ascites:** Accumulation of fluid within the peritoneal cavity (abdominal cavity containing the intestines, stomach, and liver) sometimes caused by cirrhosis.

E. **AST (or aspartate aminotransferase):** An enzyme found in a patient's blood. Additional amounts of AST are released into the blood when an organ, such as the liver, has experienced some level of tissue damage.

F. **AST to Platelet Ratio Index Score (APRI):** A score based on a calculation which is an indicator of the probability of significant liver fibrosis using the patient's AST level, the upper limit of a "normal" AST level, and platelet count.

G. **Bloodborne Pathogen:** Infectious microorganisms in human blood which can cause disease, and include, but are not limited to, Hepatitis C, Hepatitis B, and Human Immunodeficiency Virus.

H. **Boceprevir:** A drug in a class of antiviral drugs known as protease inhibitors, which was used to treat Hepatitis C for a short period of time. Boceprevir's trade name is Victrelis, and it is no longer used for treatment of Hepatitis C.

I. **Bowel Obstruction:** A blockage that keeps food or liquid from passing through the small intestine or large intestine (colon).

J. **Clotting Factors:** Proteins in the blood that help the body control bleeding. Patients with hemophilia or other clotting disorders are frequently infused with concentrates prepared from plasma pools. Clotting factors used for infusion were not screened for the presence of Hepatitis C until the 1990s when tests became available.

K. **Dasabuvir:** One of the antiviral medications in Viekira Pak.

L. **Diabetes mellitus:** Disease commonly referred to as "diabetes" that prevents the body from producing insulin or effectively using insulin produced by the pancreas. In Type 1 diabetes, the pancreas fails to produce insulin and frequently develops in children and adolescents. In Type 2 diabetes, the body does not respond correctly to the insulin produced by the pancreas. Type 2 diabetes is most commonly diagnosed in adults and is strongly correlated who have family history of Type 2 diabetes and/or are overweight.

M. **Direct-Acting Antivirals (DAAs):** Class of drugs used for treatment of Hepatitis C, which work by disrupting the viral replication process, stopping the virus from making copies of itself. The drugs include but are not limited to those going by the trade names Harvoni (ledipasvir, sofosbuvir), Mavyret (glecaprevir/pibrentasvir), Viekira Pak (dasabuvir, ombitasvir, paritaprevir, ritonavir), Zepatier (elbasvir, grazoprevir), and Epclusa (sofosbuvir, velpatasvir). First-generation DAAs included Victrelis (boceprevir) and Incivek (telaprevir).

N. **Directly-Observed Therapy (DOT):** Medications that are administered directly by trained DOC staff, requiring that an inmate come to a pill pass or receive each dose of the medication. (*Compare* Keep On Person, Appendix ¶ GG.)

O. **Epclusa:** A pangenotypic direct-acting antiviral containing a combination of sofosbuvir and velpatasvir. Pangenotypic means that the medication can be used to treat all HCV genotypes.

P. **Esophageal Varices:** Enlarged or distended blood vessels in the esophagus (the muscular tube connecting the throat and stomach) caused by increased pressure in the portal vein secondary to cirrhosis.

Q. **Fibrosis-4 Score (FIB-4):** A score based on a calculation and is an indicator of the probability of significant liver fibrosis using the patient's age, AST level, platelet count, and ALT level.

R. **Fibrosis:** As used in this Affidavit, the term "fibrosis" refers to the accumulation of scar tissue in the liver.

S. **FibroScan (also referred to as transient elastography or ultrasound elastography):** A machine which sends ultrasonic waves through the liver to estimate the amount of fibrosis.

T. **FibroSure:** A commercially-available test performed by a validated laboratory which analyzes a patient's blood and results in a score that correlates with the percentage of fibrosis that would be seen on a liver biopsy.

U. **Formulary:** A list of preferred prescription drugs at the DOC – both generic and brand name – for use within the DOC. Formulary drugs are preferred for initial treatment of a condition. Requests for non-formulary prescription drugs (i.e., those not on the list) are reviewed and authorized when medically necessary.

V. **Genotype:** With regards to Hepatitis C, the genotype is the genetic makeup of the Hepatitis C virus which is immutable and can be thought of as the genetic fingerprint of the virus. The genotype of a patient's Hepatitis C infection will match the genotype of the individual whose blood infected the patient with Hepatitis C.

W. **Glecaprevir:** One of the antiviral medications in Mavyret.

X. **Harvoni:** Direct-acting antiviral which contains a combination of ledipasvir and sofosbuvir, and is used to treat Hepatitis C. May be administered with or without ribavirin.

Y. **Hepatic Encephalopathy:** Impairment of neuropsychiatric function oftentimes associated with cirrhosis.

Z. **HCV Antibody Test:** Test to determine whether an individual has ever been infected with the Hepatitis C virus. Results include: (1) "reactive," indicating a patient has been infected with Hepatitis C virus in the past or is currently infected; (2) "non-reactive," indicating that a patient has never been infected with Hepatitis C virus; or (3) "inconclusive," which is an indeterminate result requiring further study.

AA. **HCV RNA Test (or HCVcAg):** Test taken after HCV antibody test to determine whether a patient is actively infected with the Hepatitis C virus. (Also called a qualitative viral load test.)

BB. **Hepatitis:** Depending on usage, means either:

i. inflammation of the liver; or

ii. a family of viral infections that affect the liver, including Hepatitis A, B, and C.

CC. **Hepatitis C (HCV)**: Liver disease most commonly transferred through percutaneous exposure to the blood of another who has Hepatitis C (i.e., through sharing needles, syringes, or other equipment used to inject drugs; deep tissue needle-stick injuries; unlicensed tattooing or body piercing), which may be cleared naturally by the body or become chronic. As used in this Affidavit, the term "Hepatitis C" or "HCV" means those individuals whose bodies have not cleared the infection and have a chronic (long-term) infection.

DD. **Insulin Resistance:** Clinical condition where an individual has a subnormal glucose response to the administration of a certain concentration of insulin. For example, when injected with a certain dose of insulin, a physician may expect a patient to have a certain drop in his or her blood sugar. A patient who is insulin resistant is resistant to the effects of the insulin, and the normal response to the administered dose is reduced. A patient with insulin resistance is also resistant to the effects of the insulin produced by the pancreas.

EE. **Interferon:** Protein made by the body that is used to fight off various pathogens, including viruses, by interfering with viral replication. Interferon can also be manufactured. (*See also Pegylated Interferon,* Appendix ¶ RR.)

FF. **INR** (**international normalized ratio):** Calculation based on the results of a prothrombin time (PT) test. Used to detect a bleeding disorder or excessive clotting disorder. Certain clotting factors are produced in the liver and may be reduced in advanced liver disease leading to increased INR and risk of bleeding.

GG. **Keep On Person (KOP):** Medications an inmate is allowed to keep in his or her possession without obtaining each dose from trained DOC staff. (*Compare* Directly-Observed Therapy, Appendix ¶ N.)

HH. **Ledipasvir:** One of the antiviral medications in Harvoni.

II. **Mavyret:** Direct-acting antiviral which contains a combination of glecaprevir and pibrentasvir, and is used to treat Hepatitis C.

JJ. **Non-formulary:** A prescription drug that is not on the DOC's list of prescription drugs at the DOC – both generic and brand name – for use within the DOC. Non-formulary drugs are typicaly used when a formulary drug is not effective or unavailable. Requests for non-formulary prescription drugs are reviewed and authorized when medically necessary.

KK. **NS5a resistance testing:** Detects whether an individual has a mutation to the NS5a gene. A mutation to this gene is associated with resistance to NS5a inhibitors that are included in certain direct-acting antivirals.

LL. **Olysio:** Direct-acting antiviral. Trade name for simeprevir.

MM. **Ombitasvir:** One of the antiviral medications in Viekira Pak.

NN. **Omentum:** Membranous double layer of fatty tissue that covers and supports the intestines and organs in the lower abdominal area.

OO. **Paritaprevir:** One of the antiviral medications in Viekira Pak.

PP. **Peg-Intron:** Trade name for pegylated interferon alfa-2b.

QQ. **Pegasys:** Trade name for pegylated interferon interferon alfa-2a.

RR. **Pegylated Interferon:** A medication used to treat Hepatitis C that was generally used in combination with ribavirin and or antother hepatitis C treatment medication.. Interferon is produced naturally as part of the body's immune response. Pegylation is a process through which polyethylene glycol is bonded to the interferon molecule, which makes the interferon stay in the bloodstream much longer. Two kinds are available for treatment of Hepatitis C: peginterferon alfa-2a (trade name Pegasys) and peginterferon alfa-2b (trade name PegIntron). The primary difference between peginterferon alfa-2a and peginterferon alfa-2b is the dosing schedule.

SS. **Pibrentasvir:** One of the antiviral medications in Mavyret.

TT. **Platelets:** Blood component that assists the body in forming clots to stop bleeding.

UU. **Renal Insufficiency:** Poor kidney function that can be divided into acute and chronic phases. Kidneys filter blood through a complex system that produce urine. Acute renal insufficiency is generally fairly mild, temporary, and has numerous causes. Chronic renal insufficiency occurs with longer-term damage to kidney such that they cannot filter.

VV. **Ribavirin:** Antiviral medication used for treatment of Hepatitis C in combination with other medications, such as simeprevir, sofosbuvir, or pegylated interferon.

WW. **Sensitivity:** The rate at which a test correctly identifies those with a disease.

XX. **Septicemia:** A life-threatening complication where bacteria from another infection enters the blood and spreads throughout the body.

YY. **Simeprevir:** One part of a triple antiviral treatment for Hepatitis C and direct-acting antiviral used in combination with pegylated interferon and ribavirin. Trade name Olysio.

ZZ. **Sofosbuvir:** Antiviral medication used in combination with other drugs for treatment of Hepatitis C. Sofosbuvir is sole medication in the drug with the trade name Sovaldi, and is one of the medications in the combination medications with the trade names Harvoni and Epclusa. Sofosbuvir is often used with other drugs such as ribavirin with or without pegylated interferon.

AAA. **Sovaldi:** Direct-acting antiviral. Trade name for sofosbuvir.

BBB. **Specificity:** The rate at which a test correctly identifies those without a disease.

CCC. **Standing Order:** Directions that correspond to specific health conditions requiring a course of action that may include medications, treatments, lab work, immunizations, or other interventions as indicated. A registered nurse may authorize the initiation of a standing order. The order may not be extended or renewed by a nurse a

consecutive time, and a practitioner must be notified for further evaluation and to provide a medical order for continued use in that practitioner's medical judgment.

DDD. **Steatohepatitis:** Fatty liver disease. Disease can be categorized either as nonalcoholic steatohepatitis (NASH) or alcoholic steatohepatitis. NASH develops in patients with risk factors such as obesity, dyslipidemia, or glucose intolerance. Alcoholic steatohepatitis is caused by chronic, excessive, and prolonged alcohol intake.

EEE. **Supervised Release Date:** the date on which an inmate is released from their prison sentence behind bars to serve the remaining portion of their sentence on supervised release. On DOC forms, the term "supervised release date" is sometimes abbreviated to "SVR," but the abbreviation as used in this Affidavit has the meaning described herein at ¶ WW.

FFF. **Sustained Virologic Response (SVR):** Virologic response means the absence of hepatitis C virus in the blood during treatment. When the virus is not detectable 12 or more weeks after the completion of treatment, there is a sustained virologic response. Patients who achieve a sustained virologic response are most often considered cured. A patient who has achieved a sustained virologic response cannot transmit HCV, but can become re-infected with HCV upon re-exposure. Patients who achieve SVR very rarely relapse.

GGG. **Telaprevir:** A drug in a class of antiviral drugs known as protease inhibitors, which was used to treat Hepatitis C for a short period of time. Telaprevir's trade name is Incivek, and it was withdrawn from the market in late 2014.

HHH. **Treatment Naïve:** A patient who has never been treated for Hepatitis C with any previous treatment regimen, including interferon, pegylated interferon, ribavirin, or any direct-acting antiviral.

III. **Ultrasound elastography:** A machine which sends ultrasonic waves through the liver to estimate the amount of fibrosis.

JJJ. **Victrelis:** A drug in a class of antiviral drugs known as protease inhibitors, which was used to treat Hepatitis C for a short period of time. Trade name for boceprevir.

KKK. **Viekira Pak:** Direct-acting antiviral which contains a combination of dasabuvir, ombitasvir, paritaprevir, and ritonavir, and is used to treat Hepatitis C. May be administered with or without ribavirin.

LLL. **Viral Load:** The amount of Hepatitis C virus in the blood. Measured by a blood test referred to as an HCV quantitative viral load, which measures the amount of Hepatitis C virus in one milliliter of blood and expressed as International Units (IU/mL). Results are expressed as a specific number. A viral load test does not provide any information about the severity of a patient's liver disease or degree of fibrosis. When comparing one quantitative viral load test to another, medical practitioners refer to the decrease in viral load with reference to a logarithmic scale as a log drop. A log drop is measured such as 10^5. For example, a decrease in a patient's viral load of 1,000,000 to 100,000 would be described as a one log drop, or a decrease of 90% or a decrease in a patient's viral load of 1,000,000 to 10,000 would be described as a two log drop, or a decrease of 99%.

MMM. **Zepatier:** Direct-acting antiviral which contains a combination of elbasvir and grazoprevir. May be administered with or without ribavirin.